



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

773
Isu

Applicant : Ola Karlsson et al.
 Serial No. : 10/511,115
 Filing or §371 Date : June 23, 2005
 For : FILM COATING
 Examiner : Ives J. Wu
 Group Art Unit : 1713

Certificate of Mailing Under 37 C.F.R. § 1.8

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to:

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

John M. Genova 32,224

Agent Name PTO Reg. No.

John M. Genova *26 August 2005*
 Signature Date of Signature

**Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450**

**INFORMATION DISCLOSURE
 STATEMENT UNDER 37 C.F.R. §1.97(b)(3)**

Sir:

Applicants submit this communication in compliance with 37 C.F.R. §§1.56, 1.97 and 1.98. Favorable consideration of the documents cited on the attached Forms PTO/SB/08A is respectfully requested.

The referenced application is the US. national stage application of international application no. PCT/GB03/01531 filed April 9, 2003. The published PCT application, i.e., International Publication Number WO 03/087180, the ISR, and the IPER were previously furnished to the Office on October 12, 2004 with the application filing papers.

As part of this communication, Applicants are providing a copy of US 5,292,522, issued March 8, 1994, to Petereit et al. as an English-language version of EP 0 403 959, and a copy of GB 1, 141, 165 as an English-language version of CH 484 960.

Copies of Cited U.S. Patent Documents are Not Provided

As announced in the Official Gazette of August 5, 2003, the requirement under 37 CFR §1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC §371 after June 30, 2003 has been waived.

Accordingly, copies of the U.S. patents and/or published patent applications cited on the attached Form PTO/SB/08A are not provided with this Information Disclosure Statement.

Time of Transmittal of Information Disclosure Statement

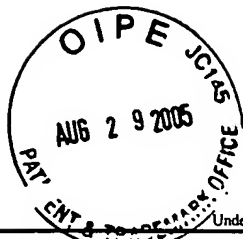
This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action and, therefore, a fee is not required in connection with the filing of this statement. However, if any fee is required, the Commissioner is authorized to charge such fee to Deposit Account No. 23-1703.

Dated: 26 August 2005

Respectfully submitted,



John M. Genova,
Reg. No. 32,224
Customer No. 007470
White & Case LLP
Direct Dial: (212) 819-8832



1103326-0781

PTO/SB/08A (08-03) (modified)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|------------------------------|---|---|---------------|--------------------------|--------------|
| Substitute for form 1449/PTO | | INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | |
| | | | | Application Number | 10/511,115 |
| | | Filing Date | June 23, 2005 | First Named Inventor | Ola Karlsson |
| | | Art Unit | 1713 | Examiner Name | Ives J. Wu |
| | | Attorney Docket Number | 1103326-0781 | | |
| Sheet | 1 | Of | 3 | | |

U.S. PATENT DOCUMENTS

| Examiner Initials [*] | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages/Figures Appear |
|--------------------------------|-----------------------|--|--------------------------------|---|--|
| | | Number-Kind Code ² (if known) | | | |
| | | 3,775,537 | 11/27/1973 | Lehmann et al. | |
| | | 4,784,858 | 11/15/1988 | Ventouras | |
| | | 5,085,866 | 02/04/1992 | Cowsar et al. | |
| | | 5,260,068 | 11/09/1993 | Chen | |
| | | 5,478,573 | 12/26/1995 | Eichel et al. | |
| | | 5,292,522 | 03/08/1994 | Petereit et al. | |
| | | 5,529,790 | 06/25/1996 | Eichel et al. | |
| | | 5,721,313 | 02/24/1998 | Yeung et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials [*] | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|--------------------------------|-----------------------|---|--------------------------------|--|---|----------------|
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | | WO 99/30685 | 06/24/1999 | Lee et al. | | |
| | | WO 99/42087 | 08/26/1999 | Nagy et al. | | |
| | | WO 00/13686 | 03/16/2000 | Wolff et al. | | |
| | | WO 00/13687 | 03/16/2000 | Wolff | | |
| | | EP 0 403 959 A1 | 12/27/1990 | Petereit et al. | | * |
| | | EP 0 217 485 A2 | 04/08/1987 | Ruffner | | |
| | | EP 0 228 879 A2 | 07/15/1987 | Morita et al. | | |
| | | CH 484 960 A | 03/13/1970 | Derra et al. | | * |
| | | GB 1,141,165 | 01/29/1969 | Derra et al. | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials [*] | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T |
|--------------------------------|----------|--|---|
| | | YOSHINOBU FUKUMORI et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. III. 1) Aqueous Coating with Ethyl Acrylate-Methyl Methacrylate-2-Hydroxyethyl Methacrylate Copolymer and the Dissolution Properties of the Products"; Chem. Pharm. Bull., vol. 36, 3070-3078, (1988). | |
| | | Abstract of JP 01-113322 A, Tomoaki et al, issued January 31, 1970, publication of application February 5, 1988. | * |
| | | HIDEKI ICHIKAWA et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. VI. 1) Microencapsulation Using Blend and Composite Latices of Copoly (Ethyl Acrylate-Methyl Methacrylate-2-Hydroxyethyl Methacrylate)"; Chem. Pharm. Bull., vol. 42, no. 6, 1308-1314, (1994). | |
| Examiner Signature | | Date Considered | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

| | | | | | |
|---|---|----|--------------------------|---------------|--|
| Substitute for form 1449/PTO | | | Complete if Known | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | Application Number | 10/511,115 | |
| | | | Filing Date | June 23, 2005 | |
| | | | First Named Inventor | Ola Karlsson | |
| | | | Art Unit | 1713 | |
| | | | Examiner Name | Ives J. Wu | |
| | | | Attorney Docket Number | 1103326-0781 | |
| Sheet | 2 | of | 3 | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|---|---|
| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T |
| | | HIDEKI ICHIKAWA et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. V. I) Agglomeration and Efficiency in the Coating with Aqueous Latices of Copoly (Ethyl Acrylate-Methyl Methacrylate-2-Hydroxyethyl Methacrylate)"; Chem. Pharm. Bull., vol. 41, no. 6, 1132-1136, (1993). | |
| | | RAGNARSSON et al., "Development of a New Controlled Release Metoprolol Product"; Drug Development and Industrial Pharmacy, vol. 13, no. 9-11, 1495-1509, (1987). | |
| | | SANDBERG et al., "Design of a New Multiple-Unit Controlled-Release Formulation of Metoprolol – Metoprolol CR"; European Journal of Clinical Pharmacology, vol. 33, no. 33, 3-7, (1988). | |
| | | SANDBERG et al., "Pharmacokinetic and Pharmacodynamic Properties of a New Controlled –Release Formulation of Metoprolol: A Comparison with Conventional Tablets"; European Journal of Clinical Pharmacology, vol. 33, no. 33, 9-14, (1988). | |
| | | RAGNARSSON et al., "In Vitro Release Characteristics of a Membrane-Coated Pellet Formulation – Influence of Drug Solubility and Particle Size"; International Journal of Pharmaceutics, vol. 79, 223-232, (1992). | |
| | | SANDBERG et al., "Influence of Dissolution Rate on the Extent and Rate of Bioavailability of Metoprolol"; International Journal of Pharmaceutics, vol. 68, 167-177, (1991). | |
| | | SANDBERG et al., "Steady-State Bioavailability and Day-to-Day Variability of Multiple-Unit (CR/ZOK) and a Single Unit (OROS) Delivery System of a Metoprolol After Once-Daily Dosing"; Pharmaceutical Research, vol. 10, no. 1, 28-34, (1993). | |
| | | SANDBERG et al., "Pharmacokinetics of Metoprolol Enantiomers after Administration of the Racemate and the S-Enantiomer as Oral Solutions and Extended Release Tablets"; Drug Invest, vol. 6, no. 6, 320-329, (1993). | |
| | | SANDBERG, "Extended-Release Metoprolol"; Thesis, Uppsala University, (1994). | |
| | | PETEREIT et al., "Formulation and Process Considerations Affecting the Stability of Solid Dosage Forms Formulated with Methacrylate Copolymers"; European Journal of Pharmaceutics and Biopharmaceutics, vol. 47, 15-25, (1999). | |
| | | PETEREIT et al., "Glyceryl Monostearate as a Glidant in Aqueous Film-Coating Formulations"; European Journal of Pharmaceutics and Biopharmaceutics, vol. 41, no. 4, 219-228, (1995). | |
| | | AMIGHI et al., "Influence of Curing Conditions on the Drug Release Rate from Eudragit NE30D Film Coated Sustained-Release Theophylline Pellets"; S.T.P. Pharma Sciences, vol. 7, no. 2, 141-147, (1997). | |
| | | BODMEIER et al., Mechanical Properties of Dry and Wet Cellulosic and Acrylic Films Prepared from Aqueous Colloidal Polymer Dispersions Used in the Coating of Solid Dosage Forms"; Pharmaceutical Research, vol. 11, no. 6, 882-888, (1994). | |
| | | OZTURK et al., Mechanism of Release from Pellets Coated with an Ethylcellulose-Based Film"; Journal of Controlled Release, vol. 14, 203-213, (1990). | |
| | | GOODHART et al., "An Evaluation of Aqueous Film-Forming Dispersions for Controlled Release"; Pharmaceutical Technology, 64-71, April (1984). | |
| Examiner Signature | | Date Considered | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. *Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A (08-03) (modified)
 Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|---|---|--------------------------|---------------|
| Substitute for form 1449/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Application Number | 10/511,115 |
| | | Filing Date | June 23, 2005 |
| | | First Named Inventor | Ola Karlsson |
| | | Art Unit | 1713 |
| | | Examiner Name | Ives J. Wu |
| | | Attorney Docket Number | 1103326-0781 |
| Sheet | 3 | of | 3 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|---|---|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T |
| | | BODMEIER et al., "Plasticizer Uptake by Aqueous Colloidal Polymer Dispersions Used for the Coating of Solid Dosage Forms"; International Journal of Pharmaceutics, vol. 152, 17-26, (1997). | |
| | | G. COLE, Table of Contents: "Pharmaceutical Coating Technology"; published by Taylor and Francis Ltd., (1995). | |
| | | GUTIERREZ ROCCA, Ph.D., "Stability and Physical-Mechanical Properties of Acrylic Resin Copolymers"; Thesis, The University of Texas at Austin, (1993). | |
| | | HJARTSTAM, "Ethyl Cellulose Membranes Used in Modified Release Formulations"; Thesis, Chalmers University of Technology, Goteborg, (1998). | |
| | | LINDSTEDT et al., "Osmotic Pumping as a release Mechanism for membrane-Coated Drug Formulations"; International Journal of Pharmaceutics, vol. 56, 261-268, (1989). | |
| | | K. KOLTER et al., "KOLLICOAT®SR 30 D - Coatings on Different Drugs"; Proceed. Int'l. Symp. Control. Rel. Bioact. Mater, vol. 27, 425-426, (2000). | |
| | | BODMEIER et al., "The Effect of Curing on Drug Release and Morphological Properties of Ethylcellulose Pseudolatex-Coated Beads"; Drug Development and Industrial Pharmacy, vol. 20, no. 9, 1517-1533, (1994). | |
| | | WILKINSON et al., "The Cleaning of Polymer Colloids"; Advances in Colloid and Interface Science, vol. 81, 77-165, (1999). | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Examiner Signature | | Date Considered | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
 *Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. *Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.